UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,868	12/03/2004	Dorothy French	146392001900	1564

25226 7590 10/10/2008

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
HIRIYANNA, KELAGINAMANE T	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
10/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,868	FRENCH ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE T. HIRIYANNA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,11,179,181,182 and 187-209* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-11, 179, 181-182 and 187-209* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 05/08/2008 in response to office action mailed on 01/08/2008 has been acknowledged.

Claims 1-9, 12-178, 180, and 183-186 were previously cancelled.

Claims 10-11, 181 and 189 are amended.

Claims 197-209 are new.

Claims 10-11, 179, 181-182 and 187-209 are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Claim Objections

Claims 10, 11, 189, and 209 recite "FGF19" while claims 179 and 190 recite "FGF-19". This use of alternative terminology is objected-to. The Applicant is required to amend all recitations to be self-consistent.

Claim Rejections - 35 USC § 112 (2nd paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11, 181, 282, 189 and 209 and their dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 11, 181,189 and 209 are indefinite as they recite " the control…transgenic mouse" as a control for a testing carried out on " a transgenic mouse" which makes the claims indefinite. If the Applicant is referring to the same transgenic mouse the applicant then should describe the appropriate conditions under which said transgenic mouse acts as a control (conditions under which it is a control for the tested one of the same kind). For example " said transgenic mouse that is untreated with said compound etc., acts as a control".

Claim Rejections - 35 USC § 112 (1st paragraph)

Claims 10, 11, 189 and their dependent claims 179, 181-182, 187-209 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a FGF19 transgenic mouse wherein said transgene is expressed under the control of a promoter in a skeletal muscle cell and wherein said transgenic mouse has a phenotype of developing Hepatocellular carcinoma (HCC), is not enabled for a HCC mouse wherein the FGF19 gene is not expressed or expressed under any cell or tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of instant invention encompasses obtaining a transgenic mouse with a phenotype of hepatocellular carcinoma (HCC) by introducing a FGF19 transgene under the control of a promoter in any tissue or cell-type. However, the specification only provides guidance and/or evidences regarding generation of a transgenic mouse with a phenotype of HCC owing to FGF19 cDNA expression driven by a MLC promoter in a skeletal muscle, its further characterization (Example 8, p.91-95) and a method of drug screening (p.96, 3rd paragraph bridging p.97-98) using said HCC mouse. The application does not disclose any other transgenic animals/mice with hepatocellular carcinoma phenotype wherein a FGF19 transgene was expressed in tissues or cell types other than the single example of skeletal muscle.

Response to Applicant's arguments in of 05/08/2008:

The Applicant amends the claims and argues that the use of any gene promoter that is linked to the FGF-19 transgene should able to induce HCC in mouse irrespective of whether the transgene is expressed or expressed at any level. Applicant further provides as examples from the art, the expression of a growth hormone gene in a transgenic animal under distinct promoters such as H2K promoter, transferring gene promoter, metallothionein gene promoter etc have resulted in the expression the growth hormone gene.

The Applicants arguments are however, found not fully persuasive. In the first place the applicant does not amend the claims to indicate that the FGF-19 gene is expressed or its expression is strictly needed for the induction said HCC phenotype in mouse. Further, the Apllicant's arguments taken from the art regarding expression of a unrelated gene (growth hormone) using distinct promoters would not suffice. The Applicant should file a declaration regarding the same indicating that the use of any promoter linked to FGF19 transgene would result in a mouse with a phenotype of Hepatocellular carcinoma (HCC). Since the specification fails to disclose other broadly claimed gene promoters that were used for driving FGF19 transgene expression in deriving a mouse with hepatocellular carcinoma, it is unclear how one skilled in the art could use the invention as claimed given the unpredictability in the art regarding use of any promoter in generating a cancer phenootype in a mouse for the reasons of record set forth in the previous office action. Hence the rejection is maintained.

Conclusion

No claim allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Kelaginamane Hiriyanna Ph.D., whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Friday from 9 AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach Ph.D., may be reached at (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

Kelaginamane T. Hiriyanna

Patent Examiner

Art Unit 1633

/Robert M Kelly/

Primary Examiner, Art Unit 1633